Appendix B to Part 236—Risk Assessment Criteria

The safety-critical performance of each product for which risk assessment is required under this part must be assessed in accordance with the following minimum criteria or other criteria if demonstrated to the Associate Administrator for Safety to be equally suitable:

(a) *How are risk metrics to be expressed?* The risk metric for the proposed product must describe with a high degree of confidence the accumulated risk of a train control system that operates over the designated life-cycle of the product. Each risk metric for the proposed product must be expressed with an upper bound, as estimated with a sensitivity analysis, and the risk value selected must be demonstrated to have a high degree of confidence.

(b) *How does the risk assessment handle interaction risks for interconnected subsystems/components?* The risk assessment of each safety-critical system (product) must account not only for the risks associated with each subsystem or component, but also for the risks associated with interactions (interfaces) between such subsystems.

(c) *What is the main principle in computing risk for the previous and current conditions?* The risk for the previous condition must be computed using the same metrics as for the new system being proposed. A full risk assessment must consider the entire railroad environment where the product is being applied, and show all aspects of the previous condition that are affected by the installation of the product, considering all faults, operating errors, exposure scenarios, and consequences that are related as described in this part. For the full risk assessment, the total societal cost of the potential numbers of accidents assessed for both previous and new system conditions must be computed for comparison. An abbreviated risk assessment must, as a minimum, clearly compute the MTTHE for all of the hazardous events identified for both previous and current conditions. The comparison between MTTHE for both conditions is to determine whether the product implementation meets the safety criteria as required by subpart H or subpart I of this part as applicable.

(d) *What major system characteristics must be included when relevant to risk assessment?* Each risk calculation must consider the total signaling and train control system and method of operation, as subjected to a list of hazards to be mitigated by the signaling and train control system. The methodology requirements must include the following major characteristics, when they are relevant to the product being considered:

(1) Track plan infrastructure, switches, rail crossings at grade and highway-rail grade crossings as applicable;

(2) Train movement density for freight, work, and passenger trains where applicable and computed over a time span of not less than 12 months;

(3) Train movement operational rules, as enforced by the dispatcher, roadway worker/Employee in Charge, and train crew behaviors;

(4) Wayside subsystems and components;

(5) Onboard subsystems and components;

(6) Consist contents such as hazardous material, oversize loads; and

(7) Operating speeds if the provisions of part 236 cite additional requirements for certain type of train control systems to be used at such speeds for freight and passenger trains.

(e) *What other relevant parameters must be determined for the subsystems and components?* In order to derive the frequency of hazardous events (or MTTHE) applicable for a product, subsystem or component included in the risk assessment, the railroad may use various techniques, such as reliability and availability calculations for subsystems and components, Fault Tree Analysis (FTA) of the subsystems, and results of the application of safety design principles as noted in Appendix C to this part. The MTTHE is to be derived for both fail-safe and non-fail-safe subsystems or components. The lower bounds of the MTTF or MTBF determined from the system sensitivity analysis, which account for all necessary and well justified assumptions, may be used to represent the estimate of MTTHE for the associated non-fail-safe subsystem or component in the risk assessment.

(f) *How are processor-based subsystems/components assessed?* (1) An MTTHE value must be calculated for each processor-based subsystem or component, or both, indicating the safety-critical behavior of the integrated hardware/software subsystem or component, or both. The human factor impact must be included in the assessment, whenever applicable, to provide the integrated MTTHE value. The MTTHE calculation must consider the rates of failures caused by permanent, transient, and intermittent faults accounting for the fault coverage of the integrated hardware/software subsystem or component, phased-interval maintenance, and restoration of the detected failures.

(2) Software fault/failure analysis must be based on the assessment of the design and implementation of all safety-related software including the application code, its operating/executive program, COTS software, and associated device drivers, as well as historical performance data, analytical methods and experimental safety-critical performance testing performed on the subsystem or component. The software assessment process must demonstrate through repeatable predictive results that all software defects have

been identified and corrected by process with a high degree of confidence.

(g) *How are non-processor-based subsystems/components assessed?* (1) The safety-critical behavior of all non-processor-based components, which are part of a processor-based system or subsystem, must be quantified with an MTTHE metric. The MTTHE assessment methodology must consider failures caused by permanent, transient, and intermittent faults, phase-interval maintenance and restoration of operation after failures and the effect of fault coverage of each non-processor-based subsystem or component.

(2) MTTHE compliance verification and validation must be based on the assessment of the design for adequacy by a documented verification and validation process, historical performance data, analytical methods and experimental safety-critical performance testing performed on the subsystem or component. The non-processor-based quantification compliance must be demonstrated to have a high degree of confidence.

(h) *What assumptions must be documented for risk assessment?* (1) The railroad shall document any assumptions regarding the derivation of risk metrics used. For example, for the full risk assessment, all assumptions made about each value of the parameters used in the calculation of total cost of accidents should be documented. For abbreviated risk assessment, all assumptions made for MTHHE derivation using existing reliability and availability data on the current system components should be documented. The railroad shall document these assumptions in such a form as to permit later comparisons with in-service experience.

(2) The railroad shall document any assumptions regarding human performance. The documentation shall be in such a form as to facilitate later comparisons with in-service experience.

(3) The railroad shall document any assumptions regarding software defects. These assumptions shall be in a form that permit the railroad to project the likelihood of detecting an in-service software defect. These assumptions shall be documented in such a form as to permit later comparisons with in-service experience.

(4) The railroad shall document all of the identified safety-critical fault paths to a mishap as predicted by the safety analysis methodology. The documentation shall be in such a form as to facilitate later comparisons with in-service faults.

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Appendix C to Part 236—Safety Assurance Criteria and Processes

(a) *What is the purpose of this appendix?* This appendix provides safety criteria and processes that the designer must use to develop and validate the product that meets safety requirements of this part. FRA uses the criteria and processes set forth in this appendix to evaluate the validity of safety targets and the results of system safety analyses provided in the RSPP, PSP, PTCIP, PTCDP, and PTCSP documents as appropriate. An analysis performed under this appendix must:

(1) Address each of the safety principles of paragraph (b) of this appendix, or explain why they are not relevant, and

(2) Employ a validation and verification process pursuant to paragraph (c) of this appendix.

(b) *What safety principles must be followed during product development?* The designer shall address each of the following safety considerations principles when designing and demonstrating the safety of products covered by subpart H or I of this part. In the event that any of these principles are not followed, the PSP or PTCDP or PTCSP shall state both the reason(s) for departure and the alternative(s) utilized to mitigate or eliminate the hazards associated with the design principle not followed.

(1) *System safety under normal operating conditions.* The system (all its elements including hardware and software) must be designed to assure safe operation with no hazardous events under normal anticipated operating conditions with proper inputs and within the expected range of environmental conditions. All safety-critical functions must be performed properly under these normal conditions. The system shall operate safely even in the absence of prescribed operator actions or procedures. The designer must identify and categorize all hazards that may lead to unsafe system operation. Hazards categorized as unacceptable, which are determined by hazard analysis, must be eliminated by design. Best effort shall also be made by the designer to eliminate by design the hazards categorized as undesirable. Those undesirable hazards that cannot be eliminated should be mitigated to the acceptable level as required by this part.

(2) *System safety under failures.*

(i) It must be shown how the product is designed to eliminate or mitigate unsafe systematic failures—those conditions which can be attributed to human error that could occur at various stages throughout product development. This includes unsafe errors in the software due to human error in the software specification, design, or coding phases; human errors that could impact hardware design; unsafe conditions that could occur because of an improperly designed human-machine interface; installation and maintenance errors; and errors associated with making modifications.

(ii) The product must be shown to operate safely under conditions of random hardware